In the United States Court of Federal Claims

No. 99-589V
(Filed July 15, 2011)

* *	*	National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 - 300aa-34 (2006); petition for review; proof of causation in fact or significant aggravation, 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); findings of fact by special master, 42 U.S.C. § 300aa-12(d)(3)(A)(I); hepatitis B vaccination; onset of Crohn's disease; whether inadequacy of proof of onset of illness after administration of vaccine is sufficient to omit causation analysis under Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274 (Fed. Cir. 2005); Vaccine R. 8(b)(1).
JENNIFER LOCANE,	*	
Petitioner,	*	
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *	*	

Clifford J. Shoemaker, Vienna, VA, for petitioner. Renée J. Geaty, of counsel.

Melonie J. McCall, Washington, DC, with whom was Assistant Attorney General Tony West, for respondent.

MEMORANDUM OPINION AND ORDER

MILLER, Judge.

This case, before the court after argument on petitioner's motion for review of the special master's decision denying compensation pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 - 300aa-34 (2006) (the "Vaccine Act"). The key issues are whether the special master's factual finding that the onset of petitioner's Crohn's disease occurred prior to her hepatitis B vaccinations was arbitrary or capricious; whether, based on that finding, the special master erred by not making findings on causation under the three-prong test set forth in Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005); and whether the record contains adequate findings concerning whether significant aggravation of petitioner's Crohn's disease was precipitated by the vaccinations.

On August 4, 1999, petitioner filed a petition in the United States Court of Federal Claims for due compensation under the Vaccine Act stemming from injuries allegedly

sustained following a series of hepatitis B vaccinations. To receive compensation under the Vaccine Act, a petitioner must demonstrate that she was given a vaccine listed on the Vaccine Injury Table, 42 U.S.C. § 300aa-14 (the "Vaccine Injury Table"), and that this vaccine caused her to develop either an injury also listed on the Vaccine Injury Table that is presumed to have been caused by a vaccination or an "off-Table" injury not presumed to have been caused by the vaccines. See 42 U.S.C. § 300aa-11(c). Petitioner pleaded an off-Table injury, which requires proof of causation. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I).

FACTS

The record on review supports the recitation of facts in Special Master Christian J. Moran's opinion. Locane v. Sec'y of Health & Human Servs., No. 99-589V (Fed. Cl. Spec. Mstr. Feb. 17, 2011) ("Entitlement Decision"). Jennifer Locane ("petitioner") was born on July 14, 1983. She was adopted and lacks knowledge of the medical history of her biological family. Entitlement Decision, slip op. at 5. The Special Master found that petitioner's pediatric records show that she had typical childhood injuries and illnesses. The records of petitioner's childhood height and weight, as recorded by her doctors on standard charts, reveal that throughout her first ten years petitioner maintained an average growth rate, placing her in the fiftieth percentile for children her age. For example, as noted by the special master, see id., in 1993, at age ten, petitioner was fifty-four and one-quarter inches tall, and weighed seventy-two and one-half pounds, id.

However, beginning in her early adolescence, petitioner's growth rate began to diminish. By July 1996, when petitioner turned thirteen, her height was approximately fifty-nine and one-half inches, placing her in the twenty-fifth percentile, and she weighed eighty-two pounds, placing her in the fifteenth percentile. On August 29, 1997, when she was fourteen years old and preparing to enter high school, petitioner saw Dr. Arnold Tanis, her pediatrician, for a routine physical examination in order to qualify her to participate in high-school athletics. Petitioner's height was sixty-one inches and remained in the twenty-fifth percentile, but her weight, eighty-eight pounds, had fallen to the tenth percentile. During her examination petitioner received the first of three doses of the hepatitis B vaccine.

Within two weeks of her first vaccination, petitioner suffered stomach cramps, loose stools, nausea, and a decreased appetite. Petitioner returned to her pediatrician on November 18, 1997, because her mother "'was concerned about [weight] loss.'" Entitlement Decision, slip op. at 8 (alteration in original). At that time petitioner weighed eighty-four pounds, four pounds less than she weighed at the end of August. Petitioner's pediatrician diagnosed her as suffering from a viral illness.

During her Thanksgiving holiday, petitioner continued to have diarrhea and developed blood in her stool. When petitioner returned to her pediatrician's office on November 28, 1997, her weight had fallen to seventy-six pounds—a decrease of eight pounds in ten days. Her pediatrician concluded that petitioner had either Crohn's disease or ulcerative colitis, and referred petitioner to Dr. Mario Tano, a pediatric gastroenterologist.

Dr. Tano saw petitioner that same day. Dr. Tano noted petitioner's medical history, although his notes do not indicate the hepatitis B vaccination. Petitioner's weight was recorded as just under eighty-two pounds, and Dr. Tano noted that this placed petitioner below the fifth percentile. Dr. Tano also recorded petitioner's height, placing her between the fifth and tenth percentiles. Dr. Tano opined that petitioner was suffering from inflammatory bowel disease, and recommended that she be admitted to a hospital.

Petitioner was promptly admitted to Joe DiMaggio Memorial Regional Hospital that same day. Her weight was recorded as seventy-seven pounds. Petitioner's stool tested negative for any pathogens. On December 4, 1997, petitioner underwent a colonoscopy with biopsy, which revealed skip lesions of colitis, ulcerative lesions, and perianal fistula, all "suggestive of Crohn's disease." DX 10 at 94. On December 5, 1997, petitioner had upper gastrointestinal tract and small bowel radiographs that showed a fifteen-to-twenty centimeter nodular and irregular area in the terminal ileum, which were also "consistent with Crohn's disease." DX 10 at 28. Petitioner was discharged on December 9, 1997, and prescribed Prednisone.

On December 11, 1997, petitioner was given her second dose of the hepatitis B vaccine during a follow-up visit with her pediatrician. Petitioner also received influenza and pneumococcal vaccinations, without any adverse effects. Petitioner again saw Dr. Tano, her pediatric gastroenterologist, on December 16, 1997. Dr. Tano noted that petitioner was doing better, continued her Prednisone prescription, and recommended that she return for a follow-up visit in six weeks. Dr. Tano reduced petitioner's Prednisone dosage on December 31, 1997.

Petitioner returned to Dr. Tano's office on February 5, 1998. Her condition had improved, and Dr. Tano's impression was that her Crohn's disease exhibited signs of remission. See DX 3 at 3-4. Dr. Tano recommended weaning petitioner off her Prednisone prescription. See id. On February 6, 1998, petitioner saw her pediatrician to receive her third dose of the hepatitis B vaccine. Shortly thereafter, petitioner's condition deteriorated once again.

On March 16, 1998, Dr. Tano saw petitioner on an "'urgent basis.'" Entitlement Decision, slip op. at 9; DX 3 at 1-2. Petitioner had blood in her stool and her temperature

was 103 degrees. Dr. Tano's notes state his conclusion of "Crohn's disease with exacerbation of symptoms." DX 3 at 2. He increased petitioner's Prednisone prescription.

Petitioner filed her petition in the United States Court of Federal Claims on August 4, 1999. As a hepatitis B case, hers was part of a group of petitions that did not prove amenable to joint resolution. This case was then assigned to the special master on February 8, 2006. She filed her first set of medical records on June 29, 2006. Petitioner filed her affidavit on October 16, 2006, and her expert report from Dr. Joseph A. Bellanti on June 6, 2007. 1/

On August 6, 2007 respondent filed its Rule 4 report opposing petitioner's claim of entitlement to compensation. Respondent's report was accompanied by an expert report from Dr. Andrew S. Warner supporting its position that petitioner's Crohn's disease was not caused by the hepatitis B vaccination. The special master held a hearing on April 17, 2008, during which petitioner and Drs. Bellanti and Warner testified. Petitioner's testimony reiterated that prior to her August 1997 hepatitis B vaccination she had not experienced any intestinal problems, "not even a stomach cramp." Transcript of Proceedings, Locane v. Sec'y of Health & Human Servs., No. 99-589V, at 10 (Fed. Cl. Spec. Mstr. Apr. 17, 2008) ("Tr."). Petitioner described her illnesses following the first vaccination:

> After the vaccination, within a week or two of receiving the vaccination, I started getting stomach cramps, started feeling nausea, and having some loose stools, and a lowered appetite. I thought that that might be

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1/ The record on review indicates that petitioner did not file her medical records with her petition. The special master explained the six-year lag in the prosecution of the petition, as follows:

> For approximately six years, [petitioner's] case did not advance. During this time, counsel for petitioners, who alleged that the hepatitis B vaccine caused them an injury, and counsel for respondent attempted to establish a mechanism for resolving cases involving the hepatitis B vaccine. These efforts, although undertaken in good faith, did not succeed.
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> After the need for individual adjudication of cases became apparent, development of [petitioner's] case started in 2006.

Entitlement Decision, slip op. at 2.

> a stomach virus, so I didn't think too much of it. I was surprised because I had never had stomach problems, but I figured it was about time that I had one.
>
> After a few weeks, it still wasn't stopping. It was progressively getting worse, and it continued until I felt that it was necessary to let my mother know that this was continuing, that I was progressively losing weight. I wasn't eating anything, and that I should probably see my pediatrician.

Tr. at 12. Petitioner attributed the fact that she did not have a similar reaction following her second vaccination in December of 1997, which followed her initial hospitalization, to the fact that she "was on such a large dose of Prednisone that I doubt anything would have been noticed." Tr. at 17 (Petitioner). In response to a question from the special master about her height during middle school, petitioner stated that she was average height and petite, "but I was always a petite girl. I was always skinny, but my height was on par with other girls." Tr. at 28. Petitioner also described what she has had to endure as a consequence of her Crohn's disease during the last ten years and the toll on her livelihood:

> It's been a really tumultuous 10 years of living with Crohn's Disease. I have lived despite it, but it has certainly not made my life easy. I struggled to get off Prednisone for four and a half years. It wasn't until my freshman year in college when I relapsed and had to go see a new gastroenterologist that I was able to get off Prednisone, but at that point I had the dean of my college in my first semester of freshman year telling me to take the whole year off because I had already had to be hospitalized and was so ill. And throughout college, I mostly studied from hospital beds or from ER rooms for my terms and finals.

Tr. at 20-21.

Petitioner filed a post-hearing brief in which she argued that the hepatitis B vaccine "'can cause Crohn's disease'" and that the vaccine "'clearly caused a significant aggravation of her condition.'" Entitlement Decision, slip op. at 4 (citation omitted). The special master determined that petitioner's argument on significant aggravation was not developed sufficiently and ordered supplemental briefing on this topic. Petitioner responded with a motion to allow additional evidence and an additional hearing. Over respondent's objection the special master granted petitioner's motion, insofar as petitioner "was permitted to file a supplemental expert report addressing whether the hepatitis B vaccine significantly aggravated a pre-existing Crohn's disease." Id. On August 28, 2009, petitioner filed a supplemental expert report from Dr. Bellanti.

On October 27, 2009, petitioner filed an additional expert report from Dr. Meyer Solny. Because Dr. Solny's report did not address the pending issue of significant aggravation, the special master ordered a supplemental report from Dr. Solny, which was submitted, along with additional literature, on March 19, 2010. Respondent responded with its own supplemental report from Dr. Warner on June 8, 2010. Further briefing followed.

On February 17, 2011, the special master issued a thorough and well-reasoned decision denying compensation. As a "preliminary step" the special master concluded it was necessary to "resolve when her Crohn's disease began." Entitlement Decision, slip op. at 10. The special master explained that "[l]ogically, if [petitioner] suffered from Crohn's disease before she was vaccinated, the vaccination could not have caused her Crohn's disease." Id. at 10 n.5. The special master found by a preponderance of the evidence that petitioner had Crohn's disease prior to her August 29, 1997 vaccination. Id. at 10-11. This finding was based in large part on the testimony of Dr. Warner, which the special master credited over that of Dr. Bellanti. Id. at 11.

Petitioner's primary expert witness, Dr. Bellanti, is a professor of pediatric microbiology and immunology at Georgetown University Medical Center and is a director of the International Center for Interdisciplinary Studies of Immunology at Georgetown University. As noted by the special master, Dr. Bellanti has "extensive experience in immunology" including service as member, director, or officer of numerous professional medical societies relating to pediatrics and immunology, as well as service on the editorial boards of various scientific journals, including, *inter alia*, Pediatric Research, Annals of Allergy, Asthma & Immunology, and Allergy Proceedings. Entitlement Decision, slip op. at 2; PX 22 at 16-17 (Dr. Bellanti's *curriculum vitae*). He has published over 400 original articles in peer review journals, over twenty books and book chapters, and is the author of a textbook of immunology. PX 22 at 23-52; Tr. at 34.

After a thorough review of petitioner's medical history, Dr. Bellanti's analysis concluded, as follows:

> This record clearly shows a temporal relationship between the hepatitis B vaccination and the development of Crohn's disease in [petitioner] as her Petition states. She received a Hepatitis B vaccination on August 29, 1997 and the note relates her symptoms to the time of that vaccination. See Exhibit 3 at 11-13. In addition, there are multiple, sometimes contradictory, notes suggesting [petitioner] had immune dysfunction, which might well predispose her to a vaccination reaction.

PX 22 at 10. Dr. Bellanti acknowledged that "evidence for vaccination causing Crohn's disease in the literature is sparse at best." Id. Following a lengthy and technical quotation from Cecil's Textbook of Medicine––but without any explanation or analysis—Dr. Bellanti concluded that "it seems clear that any antigen that could set off an inflammatory cascade, like an infection or a vaccination theoretically could cause Crohn's disease." Id. Finally, Dr. Bellanti observed that "60% of patients with Crohn's disease have antibodies to Saccharomyces cerevesiae, the yeast that carries the HBsAG in the Recombinant Hepatitis B vaccination. In addition, there is an aluminum adjuvant." Id. 2/ Dr. Bellanti recommended exploring whether petitioner had anti-Saccharomyces cerevesiae antibodies ("ASCA"). Because the hepatitis B vaccine is cultured in yeast, if petitioner did have ASCA, then "it is more likely than not that she had a vaccine reaction given the temporal relationship. The literature suggests [ASCA] are not inducible by oral ingestion of yeast, at least in the mouse model." Id.

Respondent's expert, Dr. Warner, is Chairman of the Department of Gastroenterology for the Lehey Clinic and an Associate Clinical Professor of Medicine at Tufts University School of Medicine. RX B at 1. Dr. Warner is board certified in gastroenterology and is a fellow at the American College of Gastroenterology. He is a member of the Crohn's and Colitis Foundation of America, served on the editorial board of Inflammatory Bowel Diseases, published eighteen articles, and co-authored the book 100 Questions and Answers About Crohn's disease and Ulcerative Colitis: The Lahey Clinic Guide (2007). See RX B. Over the past eighteen years, Dr. Warner has specialized in Crohn's disease at the Lehey Clinic, where he spends approximately eighty percent of his time treating patients, almost all of whom "have inflammatory bowel disease, Crohn's disease or ulcercolitis." Tr. at 102.

Dr. Warner's report disputed petitioner's theory that the hepatitis vaccination caused her Crohn's disease. In addition to arguing that there is "no evidence in the medical or scientific literature that supports the claim that the hepatitis B vaccine can either cause or exacerbate Crohn's disease," Dr. Warner dismissed the "temporal relationship to [petitioner's] receiving the hepatitis B vaccine [as] probably coincidental" because Crohn's disease "has its peak onset in adolescence." RX A at 1. More important to Dr. Warner, however, was evidence in petitioner's medical records—specifically, her growth charts—evincing a "reduction in growth velocity (i.e. growth retardation, or 'falling of the growth curve') at age 13, one year prior to her receiving the hepatitis B vaccine." Id. Dr. Warner's report explained that "[a] reduction in growth velocity is commonly the first sign

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2/ The special master explained that "Saccharomyces cerevesiae is a species of yeast used in baking and brewing." Entitlement Decision, slip op. at 3 (citing Dorland's Illustrated Medical Dictionary 1649 (30th ed. 2002)).

of Crohn's disease seen in the pediatric population, with gastrointestinal symptoms manifesting at a later date." Id. Dr. Warner concluded from petitioner's reduced growth velocity that she had Crohn's disease prior to her hepatitis B vaccination. As such, "the administration of the vaccine neither caused nor aggravated her condition based on the medical literature and my clinical experience." Id. Dr. Warner buttressed his report with a graph plotting petitioner's growth in height and weight and with several articles on Crohn's disease.

Dr. Warner also addressed Dr. Bellanti's report. After noting that Dr. Bellanti "does not site a single study or report," he dismissed Dr. Bellanti's conclusions as "Dr. Bellanti's personal opinion" that is "not supported in the medical literature, and he reiterated that "[t]here is actually no evidence in the literature linking hepatitis B vaccination to Crohn's disease." Id. at 2. Dr. Warner rejected Dr. Bellanti's ASCA theory as "nonsense." Id. He explained that "[t]he majority of patients with Crohn's disease have ASCA," the very presence of which is "one of the methods physicians use to diagnose Crohn's disease and in no way suggests any etiology." Id.

The special master explained that two factors contributed to the persuasiveness of Dr. Warner's testimony: his qualifications and expertise in treating Crohn's disease and the special master's finding that Dr. Warner's opinion was "consistent with the published literature about Crohn's disease." Entitlement Decision, slip op. at 11.

The special master deemed Dr. Warner's credentials more persuasive than Dr. Bellanti's on this particular issue because Dr. Warner is board certified in gastroenterology and has specialized in the treatment of Crohn's disease and ulcerative colitis since 1992. Most of Dr. Warner's professional time is devoted to patient treatment, some of whom are adolescents. He sees approximately thirty to fifty patients with inflammatory bowel disease per week. See id. (citing Tr. at 101-03). In contrast, the special master found that Dr. Bellanti had "much less experience" specific to Crohn's disease. Id. (noting that Dr. Bellanti "does not routinely treat patients with Crohn's disease" and has seen "fewer than ten" Crohn's disease patients within the past five years). Given the extent of Dr. Warner's experience and expertise with Crohn's disease, the special master found his testimony more persuasive than Dr. Bellanti's. Id.

The special master next examined Dr. Warner's testimony that "a common first symptom of Crohn's disease is a decrease in growth velocity." Id. The special master summarized Dr. Warner's testimony regarding the difference between diminished growth velocity and simply being below average in size, as follows:

> [A] child who starts at the 5th percentile and continues to grow at the 5th percentile can be considered a healthy child because his (or her) growth is following an expected pattern. In contrast, a child who starts at the 75th percentile but then falls to the 25th percentile may have a disease. This child may be taller and heavier than the first child, who is in the 5th percentile, but the change in velocity is significant. The change in growth velocity is a special concern in children because children should be gaining weight as they grow. If a child's weight stays the same, this constant weight will cause the child to fall to a lower percentage compared to his or her peers.

Id. at 11-12 (citations omitted). On cross-examination Dr. Bellanti recognized that "a decrease in growth velocity may be the first sign of Crohn's disease." Id. at 12.

Petitioner's medical records showed a decrease in her rate of growth velocity prior to her hepatitis B vaccination. Between the ages of ten and fourteen, she dropped from the fiftieth percentile in height and weight to the twenty-fifth in height and the tenth in weight. Id. Here, the opinions of Drs. Warner and Bellanti differed as to which aspect of growth velocity is more compelling in a Crohn's diagnosis. Dr. Bellanti testified that Crohn's affects height more than weight, a conclusion that did not persuade the special master because it is not in accord with the medical literature. Id. In contrast, the special master credited Dr. Warner's testimony that a decrease in weight gain is more indicative of Crohn's because it was consistent with the medical literature. Id. (citing Jay A. Barth & Richard J. Grand, Crohn's Disease in Childhood & Adolescence, in Crohn's Disease, 345 (Cosimo Prantera & Burton I. Korelitz eds., 1996); Eugene J. Burbige et al., Clinical Manifestations of Crohn's Disease in Children & Adolescents, 55 Pediatrics 866, 869 (1975)).

The special master found that petitioner offered "little response" to Dr. Warner's opinion that petitioner's weight velocity decreased prior to her Crohn's diagnosis. Id. at 13. The special master explained that petitioner's argument that her pre-vaccination health was normal because she was a petite child and lost only a few pounds from the age of eleven to thirteen was not supported by the "relevant measure," which is the "rate of change, not the absolute weight." Id.

The special master credited Dr. Warner's explanation that petitioner's treating doctors failed to diagnose her Crohn's disease until after her vaccination because "treating doctors may miss the earliest signs of Crohn's disease," the detection of which involves "'subtle medicine.'" Id. (citation omitted). Again, this explanation was supported by the medical literature. See id. ("Dr. Warner quoted from one article, saying '[t]he subtlety of these non-gastrointestinal presentations often led to a lag between the onset of symptoms and the arrival of a correct diagnosis. The average delay in diagnosis was 13.7 months, with a range of one

month to seven years.'" (quoting Tr. at 111) (citing Burbige et al., supra, at 869)). Based on the testimony of Dr. Warner and the supporting medical literature, the special master found that petitioner's medical history "fits comfortably within the range of presentations" described. Id. Sixteen months elapsed between July 1996, when petitioner was thirteen years old and her weight and height gain velocity began decreasing, and November 1997, when she experienced gastrointestinal symptoms such as diarrhea, which the special master found to be "close to the average reported delay in diagnosis, which was 13.7 months." Id. at 13-14. The special master found petitioner's reliance on the fact that no treating doctor stated that her Crohn's disease began prior to her vaccination was not persuasive. Id.

The special master also considered the evidence presented by Dr. Solny. Dr. Solny is a board-certified gastroenterologist who is a fellow in the Division of Gastroenterology at the New York Hospital-Cornell Medical Center. Dr. Solny maintains a private practice in internal medicine and gastroenterology and has authored three publications. Id. at 4 (citing PX 44 (Dr. Solny's *curriculum vitae*)). The special master discounted Dr. Solny's first report, which assumed that petitioner received a hepatitis B vaccination in 1994 and then opined that she "'fell off the height and weight curves at some point afterward,'" did not adequately address whether petitioner suffered from Crohn's disease prior to her August 1997 vaccination. Id. at 14 (quoting PX 43 at 2). Dr. Solny's second report asserted that petitioner "'first displayed symptoms of her Crohn's disease in early September 1997,'" id. (quoting PX 45 at 1), and did not address Dr. Warner's opinion that petitioner was suffering from Crohn's disease prior to her August 1997 vaccination; in fact, it did not include any discussion about the change in petitioner's growth curve, id. at 15 ("If Dr. Solny had expressed a reasoned disagreement with Dr. Warner's opinion, Dr. Solny's opinion might have been persuasive.").

Accordingly, the special master ruled that Dr. Warner's opinion was "not rebutted by anyone with meaningful experience in treating Crohn's disease." Id. at 16. Having found that petitioner's disease began before her vaccination, the vaccine could not have caused her disease. Therefore, the special master determined that it was not necessary to conduct an analysis under Althen, 418 F.3d at 1278. See Entitlement Decision, slip op. at 16 n.9. The special master proceeded to consider whether, pursuant to 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I), the hepatitis B vaccination significantly aggravated her Crohn's disease, see id. at 16-19, a question the special master deemed "ancillary" to petitioner's theory that the vaccination was the causative agent, id. at 17 n.10. 3/ As with petitioner's "primary"

3/ Although petitioner asserts that the special master first urged petitioner to adopt the significant aggravation theory, see Pet'r's Br. filed Mar. 21, 2011, at 17 ("The special master specifically asked [petitioner] to address the issue of significant aggravation."), it

causation theory, the special master found that petitioner's significant aggravation theory was not supported by a preponderance of the evidence. The special master applied a "but-for" standard of proof, explaining that, in order to be compensated under the significant aggravation theory, petitioner must show that the vaccine made petitioner's condition "worse than the person would have been but for the vaccination." Id. at 17 (citing Loving v. Sec'y of the Dep't of Health & Human Servs., 86 Fed. Cl. 135, 144 (2009)). The "natural course of the disease must be considered" under this evaluation. Id. (citing Hennessey v. Sec'y of Health & Human Servs., No. 01-190V, 2009 WL 1709053, at *41-42 (Fed. Cl. Spec. Mstr. May 29, 2009), motion for review denied, 91 Fed. Cl. 126 (2010)).

Again relying on the testimony of Dr. Warner, the special master found that the course of petitioner's disease was not affected by the vaccination—including her weight loss and post-vaccination gastrointestinal symptoms—because it is "'absolutely typical'" that young Crohn's disease patients have frequent flares of the disease. Id. at 17 (quoting Tr. at 139 (Warner)). In contrast, the special master found that petitioner presented "[r]elatively little evidence" to support this theory, id. at 19; see also id. at 18 ("Dr. Solny's reports do not provide any information about how [petitioner's] pre-existing Crohn's disease was worse because of the hepatitis B vaccinations."), and the special master deemed the evidence presented by Dr. Bellanti unpersuasive, id. at 18-19. Dr. Bellanti opined that petitioner's gastrointestinal flare-ups that followed her first and third vaccinations showed positive rechallenge, a circumstance in which "a positive response to repeated exposures of a substance can be evidence that the substance is affecting the recipient." Id. at 18 (citing Tr. at 76-77 (Bellanti)). The special master was not persuaded by this account due to petitioner's lack of a similar reaction following her second vaccination in December 1997 and by petitioner's experience with other similar flare-ups that were not preceded by a hepatitis B vaccine dose. Id. at 18-19. The special master inferred that "something other than the

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3/ (Cont'd from page 10.)

appears that the issue was first raised by petitioner, although in passing, see Entitlement Decision, slip op. at 16 ("[Petitioner] introduced the theory that the hepatitis B vaccine significantly aggravated her Crohn's disease when she asserted in the final paragraph of her first brief filed after the hearing that '[e]ven if the court were to find that changes in Petitioner's growth rate were somehow indicative of Crohn's Disease that was already somehow underway, then the Hepatitis B vaccines clearly caused a significant aggravation of her condition.'" (quoting Pet'r's Br. filed Aug. 25, 2008, at 11 (Fed. Cl. Spec. Mstr.))). Whether petitioner intended this idea to be taken as a serious alternative argument or not is of no moment. The special master did take it seriously and allowed petitioner to submit evidence and argument.

hepatitis B vaccine causes [petitioner] to suffer worse symptoms of Crohn's disease." Id. at 19.

Petitioner filed her Motion for Review on March 21, 2011, to which respondent filed its response on April 20, 2011. Pursuant to RCFC App. B, Rule 23(a), petitioner requests that the court set aside the special master's decision denying compensation and enter a decision in her favor; alternatively, petitioner seeks a remand to the special master. Petitioner sets forth two objections. First, the special master "arbitrarily and capriciously identified the onset of [petitioner's] Crohn's Disease on the basis of 'subtle medicine[,'] contrary to the direction of [Althen, 418 F.3d at 1278] that 'close calls' be resolved in favor of petitioner." Pet'r's Br. filed Mar. 21, 2011, at 2. Second, the special master's decision not to conduct an Althen analysis once he had determined that petitioner's Crohn's disease began prior to her hepatitis B vaccination was an abuse of discretion and not in accordance with the law. Id.

DISCUSSION

I. Standards

1. Standard of review

The Vaccine Act specifies three alternative courses of action available to the Court of Federal Claims in reviewing a special master's decision. The court may

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
> (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). The special master's findings of fact are reviewed under the deferential "arbitrary and capricious" standard. See id. § 300aa-12(e)(2)(B); de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1350-51 (Fed. Cir. 2008); Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (explaining that arbitrary and capricious standard is "particularly" difficult to satisfy when issue "turns on the weighing of evidence by the trier of fact"); Munn v. Sec'y of the Dep't of Health & Human Servs., 970 F.2d 863, 870 (Fed. Cir. 1992) (noting that arbitrary and capricious standard is "well understood to be the most deferential possible"). In contrast, the special master's conclusions

of law are reviewed without deference. Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010); Munn, 970 F.2d at 870 (explaining that "[i]ssues of law—constitutional imperatives, statutory construction, procedural requirements—come to [the United States Court of Appeals for the Federal Circuit] for decision with little if any deference owed to or expected by the forums below").

2. Proving causation in Vaccine Act cases

To be compensated under the Vaccine Act, petitioners must prove that an injury was caused by a vaccine listed on the Vaccine Injury Table set forth in 42 U.S.C. § 300aa-14. See 42 U.S.C. § 300aa-11(c)(1)(A),(C); de Bazan, 539 F.3d at 1351. The Vaccine Injury Table "lists symptoms and injuries associated with each listed vaccine and a timeframe for each symptom or injury." de Bazan, 539 F.3d at 1351. Petitioners can meet the causation burden in one of two ways. Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1149 (Fed. Cir. 2007). If petitioners demonstrate that the injury falls under the Vaccine Injury Table within the prescribed time frame, causation is presumed. See 42 U.S.C. § 300aa-11(c)(1)(C)(I); Walther, 485 F.3d at 1149. Alternatively, if the injury is not included on the Vaccine Injury Table, or falls outside the prescribed time frame for the symptom to occur, petitioners must prove by a preponderance of the evidence that the vaccine was the cause in fact of the injury. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii); Walther, 485 F.3d at 1149; see also Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1350 (Fed. Cir. 1999). Causation-in-fact is established by demonstrating by preponderant evidence "1) a medical theory causally connecting the vaccination and the injury; 2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and 3) a showing of the proximate temporal relationship between the vaccination and injury." Althen, 418 F.3d at 1278; see also Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010); Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010). Once petitioners meet their burden of proving causation in fact, thereby establishing a prima facie case for entitlement, the burden shifts to respondent to prove that the injury was caused by factors unrelated to the administration of the vaccine. 42 U.S.C. § 300aa-13(a)(1)(B); de Bazan, 539 F.3d at 1352.

II. The special master's determination that petitioner's illness began prior to vaccination

1. Petitioner's objections

Petitioner argues that the special master's determination that the onset of petitioner's Crohn's disease occurred prior to her August 29, 1997 hepatitis B vaccination was arbitrary and capricious. Pet'r's Br. filed Mar. 21, 2011, at 7. She submits that none of her treating physicians took issue with her weight prior to her vaccination and that her significant weight

loss occurred after receiving her first hepatitis B vaccine dose on August 29, 1997. Id. at 7-8. Indeed, petitioner goes so far as to state that "[p]rior to the August 1997 Hep B vaccination there was no manifestation of symptoms that justified a diagnosis of Crohn's." Pet'r's Br. filed Mar. 21, 2011, at 8.

Petitioner objects to the special master's crediting Dr. Warner's opinion that petitioner had Crohn's disease prior to the hepatitis B vaccination based on the decreased velocity of her growth rate, which petitioner contends Dr. Warner characterized as "'subtle medicine.'" Id. at 9 (quoting Tr. at 105). An article submitted by Dr. Warner, Clinical Manifestations of Crohn's Disease in Children and Adolescents, which was relied upon by the special master, see Entitlement Decision, slip op. at 13, contradicts Dr. Warner's theory and supports petitioner's, Pet'r's Br. filed Mar. 21, 2011, at 9. The weight loss of children and adolescents suffering from Crohn's disease reported in the article ranged from 4.52 kg (9.9 lbs) to 22.6 kg (49.82 lbs), see id. (citing Burbige et al., supra, at 868), whereas petitioner's most significant pre-vaccination weight loss from age eleven and one quarter through to her August 1997 vaccination was only three pounds, id. ("[Petitioner's] weight fluctuations during this time were never this striking or severe."). Petitioner contends that her only severe weight loss occurred following her hepatitis B vaccination, when she lost between ten to fourteen pounds between the end of August 1997 and the end of November 1997, which is consistent with Dr. Warner's article. Id. at 9. Petitioner challenges the significance that Dr. Warner ascribes to the change in her growth rate curve percentiles by pointing out that her medical records do not indicate that any concern was raised by her parents or doctors. Id. at 10. Furthermore, none of petitioner's treating doctors identified the onset of petitioner's Crohn's disease prior to her August 1997 vaccination. Id.

Petitioner argues that the articles submitted by Dr. Warner further support her theory of causation. The Burbige article states that, from the onset of symptoms, the average delay in a diagnosis of Crohn's disease ranges from one month to seven years. See Burbige et al., supra, at 869. However, petitioner's symptoms began within two weeks of her August 29, 1997 vaccination, and her December diagnosis in 1997 of Crohn's disease was within the pertinent time frame. Pet'r's Br. filed Mar. 21, 2011, at 10. Finally, petitioner points out the uncertainty of the findings of an article relied on by Dr. Warner to support his assertion that petitioner's diminished height velocity indicated an early onset of Crohn's disease. Id. According to petitioner, the article merely states that "'decreased linear growth *may* be an early sign of Crohn's Disease in children and [prepubescent] adolescents.'" Id. (quoting Tr. at 112 (quoting Marjorie E. Kanof et al., Decreased Height Velocity in Children & Adolescents Before the Diagnosis of Crohn's Disease, 95 Gastroenterology 1523, 1526 (1988))). Petitioner concludes that such "equivocation combined with a lack of a medically significant weight loss and a complete lack of acknowledgment, speculation or even concern on the part of her treating doctors clearly preclude[] a finding that [petitioner] had Crohn's

prior to her Hep B vaccinations." Id. at 10-11 (noting that viewing Dr. Warner's testimony in most favorable light "*may* put the onset of [petitioner's] Crohn's as a 'close-call'").

2. Upholding the decision

As the trial court observed in Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706 (2009), decisions from both the Federal Circuit and the Court of Federal Claims

> demonstrate a willingness to [set aside findings of fact or conclusions of law] of a special master when the special master has failed to adequately develop the record, failed to consider facts critical to the case, failed to give adequate consideration to a viable medical theory, or otherwise misapplied the law. *See, e.g.*, *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1276-77 (Fed. Cir. 2005) (affirming the Court of Federal Claims' reversal of the special master's decision and concluding that "the special master's erred as a matter of law by imposing . . . [a] heighten[ed] . . . evidentiary burden"); *Tebcherani*, *by Tebcherani v. Sec'y of HHS*, 55 Fed. Cl. 460, 477 (2003) (finding that the special master "abused his discretion by excluding from his review the very evidence he stated was necessary to assist in determining the timing of the onset of injury"); *Dickerson ex rel. Dickerson v. Sec'y of HHS*, 35 Fed. Cl. 593, 601-02 (1996) (finding the special master's failure "to obtain a complete record" to be arbitrary and capricious).

Id. at 718. However, the court cannot "substitute its judgment for that of the special master merely because it might have reached a different conclusion." Id.

For the following reasons, the court holds that the special master's factual finding that the onset of petitioner's Crohn's disease occurred prior to receiving the hepatitis B vaccination was not arbitrary or capricious. Ample record evidence supports the special master's finding that the testimony of Dr. Warner was more persuasive than that of Drs. Bellanti and Solny. As the special master explained, Dr. Warner is a board-certified gastroenterologist who has specialized in the study and treatment of Crohn's disease and ulcerative colitis for the past eighteen years. See Entitlement Decision, slip op. at 11; Tr. at 101-03(Warner). He has participated in clinical trials involving Crohn's disease and ulcerative colitis. Tr. at 102. Dr. Warner spends eighty percent of his professional time treating patients, thirty to fifty per week of whom have inflammatory bowel disease. Id. Significantly, his patients "usually start in adolescence," around thirteen to fourteen years old. Tr. at 102-03. Additionally, Dr. Warner chairs the Gastroenterology Department at the Lahey Clinic in Boston, which he joined "to set up a center in Crohn's disease." Id. at 101.

He serves on the editorial board of Inflammatory Bowel Diseases and has authored articles and a book on Crohn's disease.

Dr. Bellanti, by contrast, does not routinely treat patients with Crohn's disease, see Tr. at 65 (Bellanti), and testified that he has personally seen only two patients with Crohn's disease within the past five years, Tr. at 79. Dr. Bellanti is a highly respected professor of pediatrics and microbiology-immunology at Georgetown University Medical Center, who, as noted by the special master, has "extensive experience in immunology." Entitlement Decision, slip op. at 2. If he were called to provide an expert opinion on pediatric immunology, Dr. Bellanti's testimony most likely would be eminently persuasive. However, given the experts' differing backgrounds and Dr. Warner's knowledge that is specific to Crohn's disease, it was rational for the special master to find Dr. Warner's opinion more persuasive when Crohn's disease is the illness at issue.

Where "medical evidence [is] not definitive" the special master may rely heavily on expert medical testimony. Broekelschen, 618 F.3d at 1347. Expert medical testimony is particularly important in off-Table injury cases because "[t]he special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories." Id. (citing Lampe, 219 F.3d at 1361). "Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases." Moberly, 592 F.3d at 1325. The court can discern no arbitrariness in the special master's consideration of the different experience represented by the two experts. See Lampe, 219 F.3d at 1362 ("Those findings, which are at the core of the special master's decision in this case, are largely based on his assessments of the credibility of the witnesses and the relative persuasiveness of the competing medical theories of the case. As such, they are virtually unchallengeable on appeal."). In doing so, the special master "'considered the relevant evidence on the record, [drew] plausible inferences and articulated a rational basis for the decision.'" Id. at 1360 (quoting Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

The special master evaluated the experts' testimony in light of the relevant published literature on Crohn's disease in the record. Each of the articles cited by petitioner as supporting her theory of causation was discussed by Dr. Warner, and none provides the support that petitioner claims. While a claimant is not required to submit medical literature or epidemiological evidence to establish causation, "where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury." Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009). Critical to Dr. Warner's identification of the onset of petitioner's Crohn's disease as predating her hepatitis B vaccination was the reduction in her

growth velocity. Petitioner contends that between the age of eleven and thirteen she only lost a few pounds and that her major weight loss occurred after her first vaccination. See Pet'r's Br. filed Mar. 21, 2011, at 9. Petitioner relies on the Burbige article's report that the average weight loss range of 4.52 kg (9.9 lbs) to 22.6 kg (49.82 lbs) of children suffering from Crohn's disease. Id. (citing Burbige et al., supra, at 868).

However, it is not the fact that petitioner only lost a few pounds during this period that is significant. Dr. Warner explained that it is the change in petitioner's growth percentile compared to that of other adolescents in her age group that is indicative that something was medically wrong. As the special master stated, "The change in growth velocity is a special concern in children because children should be gaining weight as they grow. If a child's weight stays the same, this constant weight will cause the child to fall to a lower percentage compared to his or her peers." Entitlement Decision, slip op. at 12 (emphasis added). Contrary to petitioner's contention, Dr. Warner's opinion is supported by the Burbige article, the pertinent portion of which reads, in full:

> Weight loss was one of the earliest objective manifestations of disease in this series. Forty-six of 58 patients (80%) had weight loss, ranging from 4.52 to 22.6 kg. Weight loss or decrease in increment of weight gain is particularly notable in this age group where one anticipates a steady weight increase.

Burbige et al., supra, at 868 (emphasis added).

A "decrease in increment of weight gain" is precisely what petitioner experienced. Between the age of ten and fourteen, she dropped from the fiftieth percentile in height and weight to the twenty-fifth in height and the tenth in weight. See Entitlement Decision, slip op. at 12. Dr. Warner concluded that, with the benefit of hindsight since petitioner is now an adult, the only disease that she has developed that possibly accounts for the loss in growth velocity is Crohn's disease. See Tr. at 116. Dr. Bellanti dismissed the significance of petitioner's lack of weight gain, opining that petitioner was simply "petite." See Tr. at 94. Considering that this is flatly contrary to the medical literature on the record, the special master's finding Dr. Bellanti's opinion less persuasive than Dr. Warner's was neither arbitrary nor capricious.

Petitioner's reliance on another paragraph in the Burbige article as supportive of her contention that the time frame between the manifestation of her post-vaccination symptoms and her diagnoses of Crohn's lies within the time frame contemplated by the article similarly is misplaced. The article states, "The subtlety of these nongastrointestinal presentations often led to a lag between onset of symptoms and arrival at the correct diagnosis. The average

delay in diagnosis was 13.7 months, with a range of one month to seven years." Burbige et al., supra, at 869. Petitioner's use of this quoted language rather misses the point. The "symptoms" referred to are "nongastrointestinal"—for example, decreased rates of growth in adolescents. If one includes the diminished growth velocity as a symptom that went unnoticed, the article supports respondent's theory that petitioner had Crohn's disease well before her 1997 vaccination.

Petitioner also challenges as arbitrary and capricious the special master's denial of petitioner's claim because Dr. Warner's "use of . . . 'subtle medicine' . . . remains unsupported by a single treating doctor (including her gastroenterologist)." Pet'r's Br. filed Mar. 21, 2011, at 11. This is a mischaracterization of Dr. Warner's testimony. The "subtle medicine" described by Dr. Warner was his explanation of why treating physicians often overlook Crohn's, which accounts for the frequent diagnosis of Crohn's disease after the manifestation of nongastrointestinal symptoms—such as decreased growth velocity. See Tr. at 109 (Warner) ("It's very common in adolescents and children for the first symptom of Crohn's disease to what we call extra-intestinal. So you often see a child who has arthritis for two or three years until Crohn's Disease is diagnosed, or you will see someone who has unusual skin lesions which is later [sic] on they come up with Crohn's disease. In this particular case, there is really what's called — what I say is subtle medicine. It's well established that adolescents presented with Crohn's disease usually first have weight loss."). Dr. Warner was not suggesting that determining whether petitioner incurred Crohn's before or after her hepatitis B vaccination was "subtle medicine," or otherwise a "close call." Rather, he offered an explanation for why her pediatrician and parents did not raise earlier concerns about her growth rate or attributed it to Crohn's prior to her vaccination. See Tr. at 116 (Warner) (noting, in context of decreased weight-growth velocity, "that . . . is why it's often imperceptible to the patient's mother or father because the child looks fine, and they are in the same clothes as always").

Dr. Bellanti's forte is immunology; Dr. Warner is the expert in Crohn's disease; and the dispositive factual issue was whether petitioner's illness predated her first vaccination. Dr. Warner marginalized Dr. Bellanti in that regard. First, while Dr. Bellanti attributed petitioner's growth curve to her being petite, Dr. Warner rejoined that "body habitus" in the lexicon of Crohn's disease "does not mean anything." Tr. at 112. Rather, "it's not the absolute level but how fast they are growing." Id. Second, Dr. Bellanti termed "not germane" falling off the growth chart as a preexisting sign of Crohn's disease. Tr. at 89. Dr. Warner convincingly refuted this notion, and the medical literature in evidence also discredited it. Third, as mentioned previously, the special master found unsubstantiated Dr. Bellanti's opinion that a "profound growth deficiency" occurs in height, not weight. Tr. at 92; see Entitlement Decision, slip op. at 12. n.7.

Petitioner trivializes as a mere possibility Dr. Warner's opinion that petitioner's reduction in growth velocity marked the onset of her Crohn's disease. However, Dr. Warner was certain that petitioner had Crohn's disease before she was diagnosed. See, e.g., Tr. at 105 ("[T]here is evidence in the medical record that [petitioner] was falling off the growth curve, meaning losing weight and some loss of height as well, prior to the diagnosis of Crohn's Disease, meaning she had the Crohn's Disease before she was actually diagnosed with it."); Tr. at 105-06 (confirming that he holds this opinion to "a reasonable degree of certainty"); Tr. at 112 (opining that it is "absolutely typical" for someone to experience a reduction in growth velocity before the onset of gastrointestinal symptoms). 4/

Considering Dr. Warner's extensive and hands-on experience with Crohn's disease and the support provided for his opinions in the medical literature, it was not arbitrary or capricious for the special master to find his opinion persuasive. Indeed, other than reasserting the same arguments raised before the special master, petitioner points to no evidence in the record that would lead the court to question the special master's findings. Petitioner merely disagrees with the conclusions of Dr. Warner, and, by extension, the special master. However, this approach is not sufficient to show that the special master lacked a rational basis in accepting them. See Broekelschen, 618 F.3d at 1348 ("'[R]eversible error is extremely difficult to demonstrate if the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for his decision.'" (internal quotation marks omitted) (alteration in original) (quoting Hines, 940 F.2d at 1528)).

III. Whether the special master must undertake an analysis of all three prongs of *Althen* once he enters a finding of disease onset prior to vaccination

Petitioner also submits that the special master's decision not to conduct an Althen analysis once he had determined that petitioner's Crohn's disease began prior to her hepatitis B vaccination was an abuse of discretion and not in accordance with the law. Petitioner's argument is without merit. Nowhere in the statutory scheme or Federal Circuit precedent emerges a requirement that the special master conduct a causation analysis once the special master has determined that a preponderance of the evidence shows that the onset of the illness predates the vaccination. In fact, the opposite is the case. Pursuant to 42 U.S.C. § 300aa-13(a)(1), compensation should not be awarded if, on the record as a whole, the

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4/ The special master was careful to ensure that respondent did not hold petitioner to an impermissibly heightened legal burden of medical certainty, see Tr. at 106, but correctly stated that "if Dr. Warner wants to testify to medical certainty, he may," Tr. at 106. See Moberly, 592 F.3d at 1322.

evidence preponderates that the illness is due to factors unrelated to the administration of the vaccine. The court has sustained fully the special master's findings in that the onset of petitioner's Crohn's disease predated her first hepatitis B vaccination.

IV. Significant aggravation

Petitioner alternatively argues that, if she did have Crohn's disease prior to her vaccinations, then her Crohn's disease was significantly aggravated by her hepatitis B vaccinations. Accordingly, "the same theories, sequences of cause and effect and timing that apply to the initiation of an autoimmune condition also apply to a significant aggravation of an underlying, smoldering, or subclinical condition." Pet'r's Br. filed Mar. 21, 2011, at 18. Petitioner challenges the special master's requirement that petitioner show "the natural course of the disease" in order to show significant aggravation. Entitlement Decision, slip op. at 17. Instead, petitioner seizes on Dr. Warner's testimony that "[i]f [ten] people in this room had Crohn's Disease, there will be [ten] different patterns for Crohn's Disease," Tr. at 140, as support for her statement that "there is not a single expected course of Crohn's Disease," Pet'r's Br. filed Mar. 21, 2011, at 18. Rather than apply an objective standard, petitioner posits that the court "must look at [petitioner's] 'pattern'" to determine the course that petitioner's disease took surrounding her first and third vaccinations. Id. Petitioner relies on Dr. Bellanti's testimony concerning how environmental triggers impact autoimmunity in genetically predisposed patients to support her claim that "[a] virus or a viral vaccine is no less capable of triggering an exacerbation of an autoimmune response or disease, than it is of triggering the initial onset of the disease." Id. at 19. She maintains that significant aggravation is shown in the flare-ups that she experienced following her vaccinations "within a medically appropriate time-frame" and that this presents a "logical sequence of cause and effect [that] even fits the pattern of positive rechallenge that has been found to be strong proof of causation." Id.

The Vaccine Act provides that "[a] petition for compensation under the Program for a vaccine-related injury" may be brought if petitioner received a vaccine that "significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in" the Vaccine Injury Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). Relying on Loving, 86 Fed. Cl. at 144, the special master evaluated whether "the vaccine made the person worse than the person would have been but for the vaccination." Entitlement Decision, slip op. at 17 (citation omitted). Judge Lettow in Loving adopted three of the four prongs from the four-part test for significant aggravation of on-Table injuries articulated in Whitecotton v. Secretary of Health and Human Services, 81 F.3d 1099, 1107 (Fed. Cir. 1996), see Loving, 86 Fed. Cl. at 143, engrafting onto it the

proof of causation required for off-Table injuries. 5/ Additionally, the special master stated that in proving significant aggravation, "the natural course of the disease must be considered." Entitlement Decision, slip op. at 17 (citing Hennessey, 2009 WL 1709053, at *41-42).

The special master in the case at bar stopped short of conducting the Althen causation analysis with his preemptive finding that petitioner did not prove significant aggravation. Ultimately, petitioner's strongest challenge on review is her argument that Dr. Bellanti's expertise in immunology and pediatrics, Tr. at 36, 38, and anti-immune diseases with an environmental trigger, see Tr. at 48, 51, trumps Dr. Warner's in Crohn's disease. Although this issue surfaced post-hearing, Dr. Bellanti offered testimony that bears on whether petitioner's Crohn's disease was significantly aggravated by the administration of the hepatitis B vaccine under a theory of positive rechallenge. 6/ See Tr. at 64 (Bellanti) (stating that in addition to vaccination causing petitioner's Crohn's disease, "we have the added feature of positive rechallenge"); Tr. at 76 ("[I]n this case we have the additive feature of positive rechallenge.").

The Federal Circuit has explained positive rechallenge, as follows: "A rechallenge event occurs when a patient who had an adverse reaction to a vaccine suffers worsened symptoms after an additional injection of the vaccine." Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1322 (Fed. Cir. 2006). Dr. Bellanti explained positive rechallenge "from an immunologic standpoint" as meaning: "if you have been immunized

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5/ The six elements of proof required in Loving include:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

86 Fed. Cl. at 144.

6/ "Positive rechallenge" is also referred to as "challenge-rechallenge." See Doe/70 v. Sec'y of the Dep't of Health & Human Servs., No. V, 2011 WL 539133, at *13 (Fed. Cl. Spec. Mstr. Feb. 9, 2011). The parties used both terms interchangeably.

with a given antigen and you are re-exposed to the same antigen or a similar one, you get a boost in the immune response. This is a booster effect, and it occurs in a shorter period of time." Tr. at 76-77. In other words, petitioner was exposed to an antigen, the hepatitis B vaccine, and she suffered a reaction. Upon re-administration of the same vaccine, she suffered a worsening of her reaction. See Tr. at 85 (Bellanti) ("[O]nce we know what the antigen that set off the original immune response was, in this case it was the Hepatitis B antigen, one is re-exposed to that antigen it could set of an inflammatory cascade. This could either be in the form of infection or vaccination. It would hit those sensitized T-cells that have a certain receptor on them that would recognize that antigen when its readministered and set off that cascade.").

In his post-hearing report, Dr. Bellanti stated that he wished to "make sure that my opinion on the subject of significant aggravation is clear." PX 42 at 1. Dr. Bellanti then quoted from his testimony, as follows:

> [T]he current thinking of the pathogenesis of Crohn's Disease is that it's more cell-mediated, T-cell driven. Now, an alternative thing that could happen if you administer the antigen again, you not only complex the antibody, but you could stimulate the T-cells that are already sensitized. So from that standpoint you could exacerbate the disease.

Id. (quoting Tr. at 60) (internal quotation marks omitted). Dr. Bellanti explained the basis for his belief that, if petitioner did have Crohn's disease prior to her vaccinations, they "significantly aggravated her condition," as shown by her flare-ups following the first and third vaccinations. Id. (describing flare-up symptoms of stomach cramps, nausea, and loose stools as "classical signs of Crohn's"). Following the second vaccination, Dr. Bellanti opined that the fact that petitioner "did not have as dramatic a reaction . . . may be because she was on [P]rednisone at the time." Id.; see also Tr. at 86 (Bellanti) ("[Petitioner] was on Prednisone for four and a half years, from 1997 to about October or November 2001, varying doses from 20 milligrams down to about 7.5 milligrams.").

Dr. Solny's initial report, which incorrectly assumed that petitioner received her first hepatitis B vaccination in 1994, largely focused on causation and not on significant aggravation. See PX 43. At the conclusion of his report, Dr. Solny asserted that "[t]here additionally is a clear temporal association between the 2/6/98 Hepatitis B vaccination and the worsening of [petitioner's] CD." Id. at 2; see also id. at 3 ("[T]here is a logical sequence of cause and effect in this case, particularly with the evidence of re-challenge, and the timing of the symptoms and/or worsening of symptoms after the Hepatitis B vaccines occurred in an appropriate temporal relationship to the vaccines."). Dr. Solny did not elaborate or explain how the vaccine caused the worsening of petitioner's Crohn's symptoms or what the

normal course of the disease would be absent the vaccination. See id. Similarly, Dr. Solny's supplemental report stated:

> The Hepatitis B vaccination given on February 6, 1998 aggravated [petitioner's] pre-existing Crohn's disease. [Petitioner] sustained a flare of gastrointestinal symptoms within one to two weeks following the February 6, 1998 vaccination. The chronologic proximity of the vaccination to the exacerbation of symptoms supports the vaccination as the provocation of the flare.

PX 45 at 1. Dr. Solny's second report provided no information as to the expected course of Crohn's disease, nor did he suggest the symptoms experienced by petitioner were more severe than those of any other Crohn's patient.

The special master held that "a preponderance of the evidence demonstrates that [petitioner's] course was consistent with Crohn's disease and was not affected by the hepatitis B vaccinations." Entitlement Decision, slip op. at 17. Petitioner's evidence of significant aggravation consisted of the weight loss, nausea, loose stools, and diarrhea that she experienced following her first and third vaccinations. However, the special master again credited the testimony of Dr. Warner that it is "absolutely typical" for young Crohn's patients to incur frequent flares. See id. (quoting Tr. at 139 (Warner)).

The special master found that the expert evidence relied on by petitioner "failed to present persuasive evidence that separates these problems from an expected course of Crohn's disease." Id. Dr. Solny's first report omitted a discussion of the expected course of Crohn's disease, and his second report asserted that petitioner's August 29, 1997 vaccination caused her Crohn's disease without a discussion of significant aggravation. See id. at 18 ("Dr. Solny's reports do not provide any information about how [petitioner's] pre-existing Crohn's disease was worse because of the hepatitis B vaccinations."). 7/

Similarly, the special master found that Dr. Bellanti failed to provide any "basis for finding the hepatitis B vaccine made the Crohn's disease worse." Id. Dr. Bellanti's

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7/ Following the conclusion of post-hearing briefing, the special master permitted petitioner to file a supplemental report from Dr. Solny in order to explore significant aggravation. The special master twice asked for Dr. Solny's opinion on the expected course of Crohn's disease and how petitioner's symptoms compared. See Order entered Sept. 14, 2009, at 2 (Fed. Cl. Spec. Mstr.); Order entered Nov. 19, 2009, at 2 (Fed. Cl. Spec. Mstr.).

supplemental report did not discuss the expected course of Crohn's disease, but instead concluded that the sequence of petitioner's gastrointestinal flare-ups following her first and third vaccinations evinced positive rechallenge. Id. at 18 (citing Tr. at 76-77 (Bellanti)). However, the special master was not persuaded by a theory of positive rechallenge because, following petitioner's second dose of the hepatitis B vaccine on December 11, 1997, petitioner "did not experience any worsening of symptoms." Id. 8/ The special master also

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8/ In a footnote the special master stated that Dr. Bellanti's testimony failed to "directly address the second dose" and that his report only repeated petitioner's suggestion during her testimony that her steroid treatment likely accounted for the lack of a reaction to the second dose. Entitlement Decision, slip op. at 18 n.12. This is incorrect. See Tr. at 45 (Bellanti) ("Following the second vaccine, which was given on the 11th of December '97, we don't really have a good history of exacerbation, but I think we need to recall that she was on steroids. She was being aggressively treated . . . ."). The special master did not address the question of whether the Prednisone dosage amounts impacted the severity of petitioner's symptoms following her second vaccination, stating only that "[t]rying to determine whether prednisone prevented [petitioner] from experiencing an adverse reaction to the second dose of the hepatitis B vaccine is complicated because [petitioner] was also taking prednisone in February 1998, when she received the third dose of the hepatitis B vaccine." Entitlement Decision, slip op. at 18-19 n.12.

The special master specifically focused on the amount of Prednisone that petitioner was subject to at the times of her second and third vaccinations during an exchange between the special master and Dr. Bellanti. See Tr. at 86-88. The special master asked Dr. Bellanti to clarify his testimony that petitioner did not have a reaction following the second vaccination because she was on Prednisone. See Tr. at 87. Dr. Bellanti concurred that this was "a very important question, Your Honor. That would follow, yes, that is important to know that." Tr. at 87. The special master explored the issue further with Dr. Bellanti, as follows:

> SM: But it seemed like if she was on the same amount of Prednisone when she got the third Hepatitis B vaccination —
> Bellanti: Yeah.
> SM: — then we —
> Bellanti: It wouldn't fit the explanation. I agree. One would like — you know, in order to — I think it is necessary to look at that. I don't have those figures.

reasoned that a positive rechallenge theory is undermined by the fact that, since 1998, petitioner has experienced other similar flare-ups that were not preceded by a hepatitis B vaccine dose. Id. at 19 (citing PX 17 (petitioner's affidavit)). The special master concluded that "something other than the hepatitis B vaccine causes [petitioner] to suffer worse symptoms of Crohn's disease." Id.

The testimony was unclear as to whether a "normal course" for Crohn's disease can be discerned. Dr. Warner concurred with petitioner that Crohn's disease does not have a standard pattern in that some people have a tendency to have frequent flare-ups while others do not. Describing it as "protient," or changing, Tr. at 139, he testified that ten people with Crohn's disease will exhibit ten different patterns, Tr. at 139-40. However, frequent flares are standard, and he initially testified that he did not see anything that would be noteworthy in petitioner's medical history after each vaccination. Cross-examination did elicit his admission that petitioner's loss of ten pounds after the first vaccination was a "dramatic" weight loss for which he could offer no explanation. See Tr. at 151.

The testimony that petitioner relies upon in Dr. Bellanti's supplemental report as evidence of significant aggravation, PX 42 at 1 ("'Now, an alternative thing that could happen if you administer the antigen again, [is that] . . . . [Y]ou could exacerbate the disease.'" (quoting Tr. at 60) (Bellanti)), occurred in the context of a discussion about his

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8/ (Cont'd from page 24.)

Tr. at 87-88. The special master then declined petitioner's request for further testimony on this point, stating that it would be better to first determine the dosage amounts from the records. Tr. at 88.

Petitioner was being treated with different Prednisone dosage amounts during her second and third vaccinations. During her hospitalization petitioner received intravenous steroid treatment. On December 11, 1997, after her December 9, 1997 hospital discharge, when petitioner received her second vaccination, her Prednisone dosage was thirty milligrams per day. See PX 3 at 9; PX 12 at 29. On December 31, 1997, her dosage was lowered from thirty milligrams per day to twenty milligrams per day. See PX 3 at 7, 9. Approximately two weeks before her third vaccination, her dosage was lowered again, and petitioner was instructed to alternate her dosage of Prednisone between twenty milligrams and fifteen milligrams every other day. See id. at 3, 5. The undersigned cannot speculate whether such a lower steroid dosage could have any impact on petitioner's symptoms. Dr. Bellanti's cursory analysis that petitioner's Prednisone treatment "may" have played a role in reducing petitioner's symptoms is insufficient to overturn the special master.

ASCA reaction theory, see Tr. at 57-60. Omitted from Dr. Bellanti's supplemental report is his testimony immediately following the quotation, where Dr. Bellanti contradicts himself. The entire passage follows:

> Now, an alternative thing that could happen if you administer the antigen again, you not only complex the antibody, but you could stimulate the T-cells that are already sensitized. So from that standpoint you could exacerbate the disease.
>
> But again, I have no evidence for that. It was only an afterthought, and I don't think we really need it in this case. It will be an interesting study to do. I think it's a very interesting theoretical connection.

Tr. at 60 (Bellanti). During another discussion of his ASCA theory on cross-examination, Dr. Bellanti stated that he did not know whether the hepatitis B vaccination would produce "more disease." Tr. at 71.

The court is mindful that it was only due to the special master's generously affording petitioner every opportunity to make an argument that the record was expanded to include petitioner's alternate (and less preferred) theory of significant aggravation. See Order entered Aug. 28, 2008, at 2 (Fed. Cl. Spec. Mstr.) (ordering supplemental briefing on significant aggravation); Order entered Oct. 29, 2008, at 1 (Fed. Cl. Spec. Mstr.) (granting petitioner's motion to reopen evidentiary record and file additional expert reports); Pet'r's Mot. filed Sept. 26, 2008 (Fed. Cl. Spec. Mstr.) (requesting leave to reopen record to present "supplemental report from Dr. Bellanti and/or an additional report from a gastroenterologist"). Certainly, the special master was not required to accept a new expert report on point, let alone to afford petitioner over sixteen months to produce it. Respondent properly objected. If this were customary adversarial civil litigation, the special master's indulgence might have been held to exceed his discretion. However, this is the Vaccine Act, and the special master's ministrations to elicit as full a record as petitioner could develop are in the spirit of the Vaccine Act's relaxed litigation procedures.

The court rules that the special master's consideration of an expected or normal course of Crohn's Disease, which did not take into account petitioner's dramatic reaction to the first vaccination, does not render his findings arbitrary or capricious for three reasons. First, petitioner's proof through Dr. Solny did not contribute to her showing of significant aggravation. Second, the special master did not abuse his discretion in declining to hold a supplemental hearing and reopen the record after Dr. Solny submitted a nonresponsive first report and a limp second report. Third, the special master's finding that petitioner incurred flare-ups of a similar nature later in her adolescence and early adulthood rationally was

predicated on petitioner's own statements in her affidavit. See PX 17 ¶ 20 ("I was hospitalized three times in that first semester of my senior year [at college]. The third time I was admitted for approximately two weeks. I was so ill that even Prednisone wouldn't calm the Crohn's down."). Further, Dr. Warner testified that Crohn's patients will have flare-ups while they are on constant steroids. Tr. at 151-52 (Warner) ("That's why we have other treatments."); Tr. at 161 ("By virtue of the fact that they have gone to other therapies means she's not always been stable on Prednisone.").

It bears mentioning that respondent insists that petitioner must also prove causation, i.e., that the significant aggravation was not only temporally associated with, but also caused by—à la Althen—the hepatitis B vaccination. Because the court sustains the special master's findings, further inquiry is not warranted.

CONCLUSION

Based on the foregoing, the decision of the special master is sustained, and the Clerk of the Court shall enter judgment accordingly.

IT IS SO ORDERED.

/s/ Christine O.C. Miller

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Christine Odell Cook Miller
Judge